29:1162-1170 (1991); published NTIS US patent application No. 485,551; European patent application No. 465,204, published January 8, 1992; International Patent Application No. PCT/US91/01500, published September 19, 1991; International Patent Application No. PCT/EP90/02282, published July 11, 1991; International Patent Application No. PCT/DK89/00248, published May 3, 1990; International patent application No. WO92/00055, published January 9, 1992].--.

On page 7, delete the paragraph spanning lines 11-22, and replace it with the following paragraph:

--Fig. 2 is a schematic depiction of portions of the DNA sequence of the novel P39.5 encoding a single open reading frame which encodes a deduced protein of 37.7 kDa. This DNA fragment is named 7-1, and the deduced protein referred to as P7-1. The region in black is a unique region spanning about bp769 to about bp854 of SEQ ID NO: 1. The region labeled IA spans about bp 1 to about bp 309 of SEQ ID NO: 1; IB spans about bp 855 to about bp 1189 of SEQ ID NO: 1. Regions IA and IB have a 70% identity. Regions IIA, which spans about bp 310 to about bp494 of SEQ ID NO: 1 and IIB, which spans about bp 595 to about bp 769 of SEQ ID NO: 1, have a 91% identity. Regions A, which spans about bp 208 to about bp 309 of SEQ ID NO: 1, and B, which spans about bp 495 to about bp 595 of SEQ ID NO: 1, have an 84% identity. Regions B and C, which together span about bp 1090 to about bp1189 of SEQ ID NO: 1, have a 90% identity.--.

On page 8, delete the paragraph spanning lines 11-5, and replace it with the following paragraph:

--Fig. 6 is a Western blot of lysates from spirochetes of *B. burgdorferi* strains JD1 and B31, and *B. garinii* strain IP90 developed with serum from monkeys needle-inoculated (lanes 1) and tick-inoculated (lanes 2) with the JD1 spirochetes, and antibodies from the latter serum affinity purified off of whole live JD1 spirochetes (lanes 3).--.

On page 10, delete the paragraph spanning lines 4-19, and insert the following paragraph:

--The gene fragment, designated 7-1, from *Borrelia garinii* strain IP90 inserted in pBluescript II plasmid was transformed in *E. coli* and deposited with the American Type Culture Collection, 10801 University Boulevard, Manassas, Virginia ("ATCC") on June 27, 1997 under Accession No. 98478. When this gene fragment is expressed in *E. coli*, isolated as a pure protein and the protein used as an immunogen in mice, the antibody thus produced reacts with P39.5 of IP90. Other gene fragments, designated, 1-1, 3-1, 6-1, 9-1 and 12-1, from *Borrelia garinii* strain IP90 were similarly each inserted in pBluescript II plasmids, transformed in *E. coli* and deposited. These latter deposits were made with the ATCC on June 10, 1998 under Accession Nos. 98768 for 1-1, 98769 for 3-1, 98770 for 6-1, 98771 for 9-1 and 98772 for 12-1. All deposits were all made to meet the requirements of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure, and fully comply with the requirements of the United States Patent and Trademark Office for deposits for patent purposes. Sequences useful in the present invention may be obtained from these deposits.--.

D4 ✓

On pages 18-19, delete the paragraph spanning page 18, line 26 through page 19, line 15, and replace it with the following paragraph:

--The P39.5 protein of the present invention, or fragments of it, as well as the vls-like cassette string proteins or fragments thereof, may also be constructed, using conventional genetic engineering techniques as part of a larger and/or multimeric protein or protein compositions. Antigens of this invention may be in combination with *B. burgdorferi* outer surface proteins, such as OspA and OspB, or various fragments of the antigens described herein may be in combination with each other. In such a combination, the antigen may be in the form of a fusion protein. The antigen of the invention may be optionally fused to a selected polypeptide or protein, e.g. *Borrelia* antigens OspA and OspB, other *Borrelia* antigens, and proteins or polypeptides derived from other microorganisms. For example, an antigen or

✓ D5

D

polypeptide of this invention may be fused at its N-terminus or C-terminus to OspA polypeptide, or OspB polypeptide or to a non-OspA non-OspB polypeptide or combinations thereof. OspA and OspB polypeptides which may be useful for this purpose include polypeptides identified by the prior art [see, e.g. PCT/US91/04056] and variants thereof. Non-OspA, non-OspB polypeptides which may be useful for this purpose include polypeptides of the invention and those identified by the prior art, including, the *B. burgdorferi*, flagella-associated protein and fragments thereof, other *B. burgdorferi* proteins and fragments thereof, and non-*B. burgdorferi* proteins and fragments thereof.--.

D5 cont.)

On page 20, delete the paragraph spanning lines 11-16, and replace it with the following paragraph:

--A protein composition which may be a preferred alternative to the fusion proteins described above is a cocktail (i.e., a simple mixture) containing different P39.5 proteins or fragments, or different mixtures of the cassette string proteins of this invention. Such mixtures of these proteins or antigenic fragments thereof are likely to be useful in the generation of desired antibodies to *B. garinii*.--.

D6 ✓

On page 24, delete the paragraph spanning lines 3-18, and replace it with the following paragraph:

--Thus, an antibody of the invention is isolated by affinity purifying antiserum generated during an infection of a vertebrate animal, e.g., a rhesus monkey, with JD1 spirochetes, using as immunoabsorbant the native P39.5 antigen of IP90, or one or more of the cassette string proteins identified herein. Similarly, an antibody of the invention is isolated by immunizing mice with a purified, recombinant antigen of this invention, or a purified, isolated P39.5 of native origin. Monoclonal antibodies (MAbs) directed against P39.5 are also generated. Hybridoma cell lines expressing desirable MAbs are generated by well-known conventional techniques, e.g. Kohler and Milstein and the many known modifications thereof. Similarly desirable high titer antibodies are generated by applying known recombinant techniques to the monoclonal

D7 ✓

D

or polyclonal antibodies developed to these antigens [see, e.g., PCT Patent Application No. PCT/GB85/00392; British Patent Application Publication No. GB2188638A; Amit et al., Science, 233:747-753 (1986); Queen et al., Proc. Nat'l. Acad. Sci. USA, 86:10029-10033 (1989); PCT Patent Publication No. WO9007861; Riechmann et al., Nature, 332:323-327 (1988); Huse et al, Science, 246:1275-1281 (1988)]. --.

On pages 24-25, delete the paragraph spanning page 24, line 27 through page 25, line 2, and replace it with the following paragraph:

-- Alternatively, the antigens are assembled as multi-antigenic complexes [see, e.g., European Patent Application No. 0339695, published November 2, 1989] or as simple mixtures of antigenic proteins/peptides and employed to elicit high titer antibodies capable of binding the selected antigen(s) as it appears in the biological fluids of an infected animal or human. --.

On page 27, delete the paragraph spanning lines 4-15, and replace it with the following paragraph:

--In a similar embodiment, this diagnostic method involves detecting the presence of naturally occurring anti-P1-1, anti-P3-1, anti-P6-1, anti P7-1, anti-P9-1, and/or anti-P12-1 antibodies which are produced by the infected human or animal patient's immune system in its biological fluids, and which are capable of binding to the antigens of this invention or combinations thereof. This method comprises the steps of incubating one or preferably, a mixture, of these antigen(s) of this invention with a sample of biological fluids from the patient. Antibodies present in the fluids as a result of *B. burgdorferi* infection will form antibody-antigen complexes with the antigen(s). Subsequently the reaction mixture is analyzed to determine the presence or absence of these antigen-antibody complexes. The step of analyzing the reaction mixture comprises contacting the reaction mixture with a labeled specific binding partner for the antibody. --.